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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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EXAMINER

MEHTA, ASHWIN D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,334

Applicant(s)

CARLSON, THOMAS B.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1,5,7-10,12,13 and 21-23 is/are allowed.
- 6) ☐ Claim(s) 2-4,6,11,14-20 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The finality of the Office action mailed 23 January 2003 is withdrawn, and the following Non-Final Office action is set forth.
2. The objection to claims 22 and 23 is withdrawn.
3. The rejection of claim 21 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of Applicant's arguments presented in the papers received 28 April 2003 and 18 November 2002, and upon further consideration.

Claim Objections

4. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

Claim 26 attempts to limit the hybrid plant of claim 25 by requiring it to be an F₁ hybrid corn plant. However, the plant of claim 25 is the first generation progeny of the cross of two distinct inbred plants, and therefore is an F₁ hybrid plant. Claims 25 and 26 are directed to the same plant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 4, and 14 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 23 January 2003. Claims 6, 11, 15-20, 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3, 4, and 14: Applicant submits that the claims are not indefinite as set forth in the previous response to the Office action (response, page 3, 1st paragraph). The rejection is maintained, for the reasons stated in the previous Office actions.

In claim 2: the recitation "population of seed of the corn variety I015011" renders the claim indefinite. It is unclear exactly when a population can be defined as a population of I015011 seed and not a population of another seed variety. The paragraph bridging pages 5-6 of the specification states that inbred seed "generally" forms at least about 97% of total seed. The recitations "generally" and "at least about" leave the explanation open to encompass any other percentage of inbred seed. The very next sentence indicates that a population of inbred corn seed can contain 15% or less of inbred seed, and this would be indistinguishable from a small fraction, "generally" less than 2% and preferably less than 1% of inbred seed in a population of hybrid seed. If a population contains a greater percentage of seed A than seed B, is this still defined as a population of seed B, rather than a population of seed A? Applicant's discussion of "population" indicates that a population containing 85% of seed A and 15% of seed B can be defined as both a

population of seed A and a population of seed B. It is also not clear what is meant by the term "generally" in the context of the definition for "population."

In claims 6 and 11: the recitation "in accordance with" renders the claims indefinite. The meaning of this recitation is not exactly clear, and makes the metes and bounds of the claims unclear.

In claims 15, 17, and 20: the recitation "capable of expressing" in line 1 of claim 15 and line 2 of claims 17 and 20 renders the claims indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation in claim 15 be replaced with --having--, and in claim 20 with --has--. Similarly, the recitation "is capable of regenerating" in line 2 of claim 17 renders it indefinite. It is suggested that the recitation "the tissue is capable of regenerating plants capable of expressing" be replaced with --plants, when regenerated from said tissue culture, have--.

In claims 16 and 27: the claims broaden the scope of the claims from which they depend. The claims add on a gene or locus to the genome of the plant of their parent claims. There is no indication as to how the plants acquired the genes, and the plant of their parent claims do not possess the gene or locus. It is suggested that claim 16 be amended to recite that the plant was produced from the plant of claim 15, and to indicate how the cytoplasmic or nuclear gene conferring male sterility was introduced into the plant of claim 8. Claim 27 should be similarly amended.

In claim 18: the "derived from" in line 1 renders the claim indefinite. It is not clear how the cells are derived from the recited tissues. It is suggested that the term "derived" be deleted, or replaced with the term --isolated--.

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In claim 19: the recitation "the regenerable cells comprise protoplasts" renders the claim indefinite, since protoplasts are not cells. It is suggested that the recitation, "protoplasts or" be deleted from claim 19, and that claim 17 be amended by inserting the recitation, "--, or protoplasts of said cells,-- be inserted in line 1 after "cells."

In claim 22: the claim is improperly dependent on claim 21. Claim 22 recites a new process. However, to be properly dependent on claim 21, claim 22 should recite how the process of claim 21 is further limited. It is suggested that claim 22 be amended by deleting the recitation, "further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant", and inserting the recitation, "--, and said second parent corn plant is a distinct inbred corn plant-- in line 4 after "PTA-3224".

In claim 28: the article "a" in the recitation "wherein the single locus was stably inserted into a corn genome" renders the claim indefinite. The recitation does not make clear if the genome is that of I015011 or that of a different corn plant.

In claim 30: the recitations, "yield enhancement," "improved nutritional quality," and enhanced yield stability" are relative terms that have no definite meaning, and make the metes and bounds of the claim unclear.

6. Claims 3, 4, 14, 24-31 remain and claims 2, 6, and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 23 January 2003 under item 6. Applicant traverses the

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rejection in the paper received 28 April 2003. Applicant's arguments were fully considered but were not found persuasive. The rejection has been withdrawn from claim 21, upon further consideration.

Regarding claims 3, 4, 14, and 24-30, Applicant submits that the claims do not lack written description for the reasons submitted in the previous Response (response, page 4, 4th full paragraph). The rejection is maintained for the reasons of record stated in the previous Office actions. Claim 2 has been included in the rejection as other varieties of seed, which are not described, might be in the claimed population of seed of the corn variety I015011, as discussed above. Claims 6 and 11 have been included in the rejection, because written descriptions of each of the RFLP and isozyme markers have not been provided. While the markers are named, this is not sufficient to describe them.

Regarding claim 31, Applicant disagrees with the legal contention that products made in intermediate steps of method claims must be described, and ask that the legal basis with citation to the relevant legal authorities be cited (response, paragraph bridging pages 4-5). Applicants are directed to 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

5. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards inbred corn plant I015011 further defined as having a genome comprising any single locus conversion; or wherein the single locus was stably inserted into a corn genome by transformation.

The specification teaches that single locus conversions of the disclosed corn plant refers to plants that are developed through backcrosses wherein essentially all of the desired morphological and physiological characteristics of the inbred are recovered in addition to a single locus transferred by the backcrossing technique (paragraph bridging pages 29-30). However, the specification does not teach any I015011 plants comprising single locus conversions produced by crossing. The specification at pages 35-36 provides a summary of the crosses performed to introduce a locus into a DEKALB proprietary inbred corn plant. However, there is no indication that all of the morphological and physiological traits of the DEKALB proprietary inbred corn plant were recovered, and that only one single locus was transferred from the donor parent.

It is not clear that single loci may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage

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disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

The specification also teaches that single loci may be introduced by transformation (page 33, line 1-10). Claim 28 recites the recitation, "wherein the single locus was stably inserted into a corn genome by transformation" (emphasis added). This recitation does not clearly indicate that it was plant I501150 that was transformed. The claim encompasses the embodiment that another corn plant was transformed, and that the single locus was introduced into I501150 by backcrossing.

If claim 28 is directed to I015011 plants into which a single locus was directly introduced by transformation, the specification does not enable transforming I501150 cells with all types of transgenes. As broadly interpreted, the claimed plants and method encompass introducing any type of transgene into I015011, including those that have not been isolated at the time the application was filed. Claims 27-29 also encompass loci whose functions are unknown. One

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skilled in the art would not know how to use plants containing such loci. Single loci have also not been identified in the art for all of the traits listed in claim 30, as discussed above. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Further, if the effect of transgene expression in I015011 is unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Furtherstill, the effects of transgene expression on the traits expressed by untransformed I015011 are unknown. The specification does not teach one how to use a transformed I015011 plant if all of the morphological and physiological traits of I015011 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

11. Claims 1, 5, 7-10, 12, 13, and 21-23 are allowed. Claims 2-4, 6, 11, 14-20, and 24-31 are rejected.

Contact Information

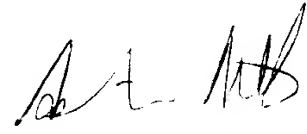
Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can

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normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

July 24, 2003



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER